

Notice of Allowability

Application No.

09/632,036

Applicant(s)

KAUMAYA ET AL.

Examiner

Art Unit

Stephen L. Rawlings, Ph.D.

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11 November 2005.
2. ☒ The allowed claim(s) is/are 3,35 and 39-42.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

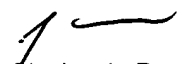
* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 20051114
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 20060120.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.


Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1643

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Andrew J. Mueller on January 20, 2006.

2. The application has been amended as follows:

In the claims:

Claims 1 and 2. (Canceled)

Claim 3. (Currently Amended) A ~~composition~~ chimeric peptide for stimulating an immune response to HER-2 protein, wherein said ~~composition is a~~ chimeric peptide and comprises a HER-2 B cell epitope, a T helper (Th) epitope, and a linker joining said HER-2 B cell epitope to said Th epitope, wherein the sequence of the HER-2 B cell epitope is SEQ ID NO: 6, wherein the Th epitope comprises a sequence selected from the group consisting of:

N-S-V-D-D-A-L-I-N-S-T-I-Y-S-Y-F-P-S-V, SEQ. ID. NO: 13;

P-G-I-N-G-K-A-I-H-L-V-N-N-Q-S-S-E, SEQ ID NO: 14;

Q-Y-I-K-A-N-S-K-F-I-G-I-T-E-L, SEQ ID NO: 15;

F-N-N-F-T-V-S-F-W-L-R-V-P-K-V-S-A-S-H-L-E, SEQ ID NO: 16;

L-S-E-I-K-G-V-I-V-H-R-L-E-G-V, SEQ ID NO: 17;

F-F-L-L-T-R-I-L-T-I-P-Q-S-L-N, SEQ ID NO: 18; and

T-C-G-V-G-V-R-V-R-S-R-V-N-A-A-N-K-K-P-E, SEQ ID NO: 19;

and wherein the linker consists of from one to fifteen amino acids.

Claims 4-34. (Canceled)

Claim 35. (Currently Amended) A ~~composition~~ chimeric peptide for stimulating an immune response to HER-2 protein, wherein said ~~composition is a~~ chimeric peptide and comprises a HER-2 B cell epitope, a T helper (Th) epitope, and a linker joining said HER-2 B cell epitope to said Th epitope; wherein SEQ ID NO: 6 is the sequence of the HER 2-B cell epitope, wherein SEQ ID NO: 17 is the sequence of the Th epitope, and wherein SEQ ID NO: 20 is the sequence of the linker.

Claims 36-38. (Canceled)

Claim 39. (Currently Amended) A ~~mixture~~ An immunogenic composition comprising the ~~composition~~ chimeric peptide of Claim 3, further comprising a second chimeric peptide wherein said second chimeric peptide comprises a HER-2 B cell epitope, a T helper (Th) epitope, and a linker joining said HER-2 B cell epitope to said Th epitope; wherein the sequence of the HER-2 B cell epitope is SEQ ID NO: 42, wherein the Th epitope comprises a sequence selected from the group consisting of:

N-S-V-D-D-A-L-I-N-S-T-I-Y-S-Y-F-P-S-V, SEQ. ID. NO: 13;

P-G-I-N-G-K-A-I-H-L-V-N-N-Q-S-S-E, SEQ ID NO: 14;

Q-Y-I-K-A-N-S-K-F-I-G-I-T-E-L, SEQ ID NO: 15;

F-N-N-F-T-V-S-F-W-L-R-V-P-K-V-S-A-S-H-L-E, SEQ ID NO: 16;

L-S-E-I-K-G-V-I-V-H-R-L-E-G-V, SEQ ID NO: 17;

F-F-L-L-T-R-I-L-T-I-P-Q-S-L-N, SEQ ID NO: 18; and

T-C-G-V-G-V-R-V-R-S-R-V-N-A-A-N-K-K-P-E, SEQ ID NO: 19;

and wherein the linker consists of from one to fifteen amino acids.

Claim 40. (Currently Amended) A ~~mixture~~ An immunogenic composition comprising the ~~composition~~ chimeric peptide of Claim 3, further comprising a second chimeric peptide wherein said second chimeric peptide comprises a HER-2 B cell epitope, a T helper (Th) epitope, and a linker joining said HER-2 B cell epitope to said

Th epitope; wherein SEQ ID NO: 42 is the sequence of the HER 2-B cell epitope, wherein SEQ ID NO: 17 is the sequence of the Th epitope, and wherein SEQ ID NO: 20 is the sequence of the linker.

Claim 41. (Currently Amended) ~~A mixture~~ An immunogenic composition comprising the ~~composition~~ chimeric peptide of Claim 35, further comprising a second chimeric peptide wherein said second chimeric peptide comprises a HER-2 B cell epitope, a T helper (Th) epitope, and a linker joining said HER-2 B cell epitope to said Th epitope; wherein the sequence of the HER-2 B cell epitope is SEQ ID NO: 42, wherein the Th epitope comprises a sequence selected from the group consisting of:

N-S-V-D-D-A-L-I-N-S-T-I-Y-S-Y-F-P-S-V, SEQ. ID. NO: 13;

P-G-I-N-G-K-A-I-H-L-V-N-N-Q-S-S-E, SEQ ID NO: 14;

Q-Y-I-K-A-N-S-K-F-I-G-I-T-E-L, SEQ ID NO: 15;

F-N-N-F-T-V-S-F-W-L-R-V-P-K-V-S-A-S-H-L-E, SEQ ID NO: 16;

L-S-E-I-K-G-V-I-V-H-R-L-E-G-V, SEQ ID NO: 17;

F-F-L-L-T-R-I-L-T-I-P-Q-S-L-N, SEQ ID NO: 18; and

T-C-G-V-G-V-R-V-R-S-R-V-N-A-A-N-K-K-P-E, SEQ ID NO: 19;

and wherein the linker consists of from one to fifteen amino acids.

Claim 42. (Currently Amended) ~~A mixture~~ An immunogenic composition comprising the ~~composition~~ chimeric peptide of Claim 35, further comprising a second chimeric peptide wherein said second chimeric peptide comprises a HER-2 B cell epitope, a T helper (Th) epitope, and a linker joining said HER-2 B cell epitope to said Th epitope; wherein SEQ ID NO: 42 is the sequence of the HER 2-B cell epitope, wherein SEQ ID NO: 17 is the sequence of the Th epitope, and wherein SEQ ID NO: 20 is the sequence of the linker.

Examiner's Statement of Reasons for Allowance

3. The following is an examiner's statement of reasons for allowance:

The prior art does not teach or fairly suggest a HER-2 B cell epitope, or peptide consisting of the amino acid sequence of SEQ ID NO: 6.

Support for the claims, as amended, is found throughout the specification, including the claims, as originally filed (e.g., page 3, lines 12-28; page 4, lines 1-24; page 6, lines 5-9; page 24, lines 16-23; page 30, lines 9-12; and original claims 1-5). In particular, support for "immunogenic compositions" comprising one or more of the disclosed chimeric peptides, including those to which the claims specifically refer, is found in the specification, as filed, for example, at page 5, lines 3-5; page 6, lines 19-22; and page 18, lines 7-9.

4. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Election/Restriction

5. The requirement to elect a species of the invention of Group I, as set forth in section 7, beginning at page 7, of the Office action mailed October 15, 2004, has been withdrawn to any extent that the claims read on a composition comprising one or more chimeric peptides, wherein said one or more chimeric peptides includes a chimeric peptide selected from the group consisting of a chimeric peptide comprising a B-cell epitope consisting of SEQ ID NO: 1, a chimeric peptide comprising a B-cell epitope consisting of SEQ ID NO: 6, and a chimeric peptide comprising a B-cell epitope consisting of SEQ ID NO: 42.

In addition, the requirement, set forth in section 12, beginning at page 7, of the Office action mailed October 15, 2004, to elect a species of the invention of Group I, wherein said T helper epitope is selected from those set forth as SEQ ID NO: 13, SEQ ID NO: 14, SEQ ID NO: 15, SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, and SEQ ID NO: 18, has been withdrawn.

Conclusion

6. Claims 3, 35, and 39-42 have been allowed.
7. Claims 3, 35, and 39-42 have been renumbered as claims 1, 4, 2, 3, 5, and 6, respectively.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1643

slr
January 20, 2006